

WO 00/53158

PCT/EP00/01773

17

CLAIMS

1. A process for modifying the surface properties of particles for use as carrier particles for the pulmonary administration of micronised drugs by means of dry powder inhalers, the process including the step of subjecting said carrier particles to a mixing treatment in a mixer equipped with a rotating element in order to produce *in situ* a fine fraction of said carrier.

2. A process according to claim 1, in which the particles of said carrier have a starting diameter ranging from 90 to 150 μm and said fine fraction of the carrier has a mean aerodynamic diameter of less than 10 μm .

3. A process according to claims 1-2 in which the mixer is selected from those with a stationary or rotating body equipped with any rotatory element (blade, screw) or the high energy ones such as "high-shear".

4. A process according to claims 1-3 in which the mixer is a sigma blade mixer and the rate of mixing is comprised between 100 and 300 r.p.m..

5. A process according to claims 1-4, in which the mixing time of the carrier powder ranges from 5 to 360 minutes.

6. A process according to claims 1-5, in which the mixing time is 30 minutes.

7. A process according to claims 1-6, in which said carrier consists of one or more saccharides.

8. A process according to claims 1-7, in which said carrier consists of α -lactose monohydrate.

9. A process according to claims 1-8, which yields a fraction of carrier particles whose variation of the starting mean aerodynamic diameter is less than 20%.

10. A process according to the preceding claims in which, after mixing in the mixer, a suitable amount of an additive selected from lubricants, anti-adherent agents and glidants is added to the carrier.

WO 00/53158

PCT/EP00/01773

18

11. A process according to claim 10, in which the amount of additive ranges from 0.05 to 2%.

12. A process according to claims 10 and 11, in which the lubricant is magnesium stearate, stearic acid, sodium stearyl fumarate or sodium benzoate.

13. A process according to the preceding claims, in which one or more active ingredients, whose particles have a mean diameter of less than 5 μm , are added to the carrier.

14. A process according to claim 13, in which the active ingredient is a β -agonist selected from salbutamol, formoterol, salmeterol, terbutaline or salts thereof.

15. A process according to claim 13, in which the active ingredient is an antiinflammatory steroid selected from beclomethasone dipropionate, flunisolide, budesonide and the epimers thereof.

16. A process according to 13 in which the active ingredient is an anticholinergic selected from ipratropium bromide or oxytropium bromide.